CASE STUDIES: DATA USE AND HIE

Case Study 1: Use of Opt-Out

Scotland's Emergency Care Summary (ECS) [1]

Scotland's country-wide exchange includes limited health care data (current medications, repeat medications, allergies, and basic demographic information). This data is currently available for emergency (out of hours) use only. Ultimately, it is likely to be available to accident and emergency departments as well. Data is extracted from patient records and held on a central data repository, the ECS Store, and updated twice a day if anything changes in the record.

ECS outlines the following two-stage consent model:

1. "Initial upload of the summary record to the central database works on implied consent with local publicity campaigns mounted to explain the concepts behind the ECS and what it will include when the summary record has been rolled out across a health board."

2. "The second stage of the consent model is that explicit consent must be gained from the patient during an out-of-hours consultation before clinicians can access the ECS."

Of note, *"out of 3.5 million records on the system, only 22 patients have opted out."*

Case Study 2: Sample Data Use Policies—Treatment, Research, and Public Health

The Indiana Network for Patient Care (INPC): Healthcare Data Sharing Agreement [2]

INPC is a citywide electronic medical records system that allows physicians in the emergency departments, with the patient's permission, to view as a single virtual record of all previous care at any of 11 hospitals. Built on the Regenstrief Medical Record System (RMRS), INPC will encompass 90% of Indianapolis' hospital emergency care when completed. It will also include a major share of the laboratory and hospital encounter data for the city.

Excerpts of its data sharing agreement (below) can help inform our discussion of data use:

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[1] "Scots Ahead," by Fiona Barr of the e-Health Insider. (April 17, 2006). Full text available online at: http://www.e-health-insider.com/comment_and_analysis/index.cfm?ID=137

[2] Excerpts of "The Indiana Network for Patient Care: A Case Study of a Successful Healthcare Data Sharing Agreement," by Christopher S. Sears Esq., Victoria M. Prescott Esq., and Clement J. McDonald MD (2005). Full text at: http://www.regenstrief.org/medinformatics/inpc/INPC_Paper

Treatment: "The partici[pating organizations] authorize Regenstrief to disclose their data to other participants when a patient presents to another participant for treatment. Both state and federal law allow broad sharing of health data between health care providers for purposes of treating a patient. Neither Indiana state law, nor the Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") requires patient consent to disclose health data for treatment purposes.

Each participant [organization] must identify those individuals under its supervision that may access data on the INPC network. These individuals may include hospital employees (e.g., hospital-based physicians, physicians with admitting privileges, nurses, etc.), but may also include individuals who work for physician groups affiliated with a hospital.

It is up to each individual participant [organization] to: (1) train their designated personnel about the confidentially of patient data; (2) ensure that the personnel will only access the INPC for treatment purposes; (3) require that the personnel hold passwords to the INPC confidentially; (4) require such personnel to participate in surveys and studies about the efficacy of the INPC; and (5) ensure that personnel understand that breaches of confidentiality may result in exclusion from the INPC and other discipline.

Personnel designated by the participants do not have unfettered access to INPC data. When a patient presents for treatment at one of the participant's treatment locations, an electronic HL7 admission message is sent from the participant to Regenstrief indicating that a patient has presented to the health care provider for treatment (e.g., presented to an emergency room, arrived for an office appointment or outpatient procedure, or been admitted as an inpatient to a hospital). A patient is under the "treatment" of a participant when a health care provider is providing, coordinating, or managing the health care of a patient. The admission message verifies that a patient has actually presented for treatment, and the participant has a right to receive information about the patient from the INPC network. At that point, the INPC system goes to work and searches each participants' files for information about the patient.

The information is aggregated and can be viewed as a single virtual medical record over a secure internet connection between Regenstrief and the requesting participant. The designated personnel may access that patient's data on the INPC network for only a limited time period to reduce any potential for misuse. For example, if a patient presents to an emergency room, the patient's data is available to the participant's designated personnel for a twenty-four hour period after the admission message is received by Regenstrief. The record can be printed in hard copy for inclusion in the participant's medical record."

Research: "INPC data may also be used for scientific research purposes. The agreement provides for the use of INPC data for research by delegating a substantial amount of responsibility to Regenstrief (a long-standing medical research institution with considerable experience in reviewing and evaluating research proposals), while maintaining appropriate levels of control by the participants over their data on the INPC

network. All of this is accomplished while still maintaining compliance with HIPAA's complicated rules relating to the use of patients' data for research purposes.

The agreement defines a hierarchy of approvals that are required before INPC data may be used for research purposes. The participants recognize that, as a research institution and a long-term custodian of a plethora of health data, Regenstrief has considerable experience working with researchers for requests to access the data. As a result, the agreement delegates to Regenstrief the authority to review research requests on behalf of the participants and, when a desirable project is identified, present the project to the participants. Subject to some exceptions, Regenstrief must obtain approvals from the participants prior to using or disclosing their data for research. Importantly, the agreement generally prevents the use of participants' data when the purpose of the study is to directly compare the participants or providers themselves. For example, without specific approval from the affected participants, data cannot be used to compare individual patient outcomes, financial information, or charges to patients on a participant-by-participant basis. This assures the participants that their data will not be used to their detriment for purposes of pitting one against the other.

First, the agreement's research provisions provide for the use of data for research projects that were specifically identifiable at the time the agreement was signed. These projects relate to the operation of the INPC itself, as well as a cancer research project known as the Shared Pathology Informatics Network. These research projects already have been subjected to review and approval by the participants and Institutional Review Boards ("IRBs").11 Data may be used for these projects without further approval from the participants.

Second, research projects that involve independent agreements between one or more participants and Regenstrief are not subject to the terms of the agreement. Thus, if one participant consents to allow the use of its data that is stored on the INPC system, a separate agreement (independent of the INPC agreement) may be executed between Regenstrief and that participant.

Third, HIPAA's Privacy Rule allows for the use and disclosure of health information without a patient's consent or approvals from an Institutional Review Board if: (1) the data is used only for uses that are preparatory to a research project; or (2) the data relates to a deceased individual. As long as the data is used consistently with HIPAA's limitations on this data, Regenstrief has the ability to use participants' data for these purposes without any further approval from the participants.

Fourth, HIPAA allows for the use of deidentified data and "limited data sets" without a patient's consent or approvals from an Institutional Review Board. The agreement delegates to Regenstrief the ability to use and disclose deidentified information and limited data sets on behalf of the participants without further approval from the participants. In other words, the participants do not have to approve the specific research project(s) for which the data will be used or disclosed. However, Regenstrief may not use or disclose such data unless the entity requesting the data has obtained an approval from

an Institutional Review Board acceptable to Regenstrief for the use of deidentified data or limited data sets (even though HIPAA's Privacy Rule would not otherwise require IRB approval).

Finally, if a research use or disclosure does not fall into one of the foregoing five categories, Regenstrief must propose it to the INPC's Management Committee (see Section 4.5 below for a discussion of the Management Committee). Any such research project must be approved by: (1) an IRB approved by Regenstrief; (2) the participants whose data is proposed to be used; and (3) Regenstrief. Any participant may decline to allow its data to be used for the research project, but that does not preclude the other participants from allowing the use of their data. Because Regenstrief maintains each participant's data in segregated files, this separation is possible.

Public Health: Indiana, like many states, requires health care providers and other entities to report certain information that impacts public health. Reporting communicable diseases, positive lead levels, or Shigella isolates are examples. The electronic HL7 feeds that participants provide to Regenstrief to populate the INPC provide an efficient way to screen for reportable events. Regenstrief filters the incoming messages for reportable conditions and reports them to Indiana and Marion County Health Departments on behalf of the participants. This public health function is enhanced through a grant funded by the Centers for Disease Control through the Indiana State Department of Health that allows Regenstrief to construct a network to capture chief complaint information and other data in real time from all 140 Indiana hospital emergency rooms for biosurveillance and outbreak detection.